Summary of risk management plan for TRISENOX (arsenic trioxide)

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Disclaimer

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risk as well as to prevent or minimize them.

The RMP summary of TRISENOX is a concise document and does not claim to be exhaustive.

As the RMP is an international document, the summary might differ from the "Arzneimittelinformation / Information sur le médicament" approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of TRISENOX in Switzerland is the “Arzneimittelinformation / Information sur le médicament” (see www.swissmedic.ch) approved and authorized by Swissmedic. Teva Pharma AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of TRISENOX.

Summary of Risk Management Plan for TRISENOX (arsenic trioxide)

This is a summary of the risk management plan (RMP) for TRISENOX (arsenic trioxide). The RMP details important risks of arsenic trioxide, how these risks can be minimised, and how more information will be obtained about arsenic trioxide´s risks and uncertainties (missing information).

Arsenic trioxide´s summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how arsenic trioxide should be used.

This summary of the RMP for arsenic trioxide should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of arsenic trioxide´s RMP.

I. The Medicine and What It is used for

TRISENOX is authorised for induction of remission, and consolidation in adult patients with acute promyelocytic leukaemia (APL) (see SmPC for the full indication). It contains arsenic trioxide as the active substance, and it is given as an infusion into a vein.

Further information about the evaluation of TRISENOX´s benefits can be found in TRISENOX´s Swiss-SmPC: https://www.swissmedicinfo.ch/.

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of arsenic trioxide, together with measures to minimise such risks and the proposed studies for learning more about arsenic trioxide´s risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine’s packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine’s legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

II.A List of Important Risks and Missing Information

Important risks of TRISENOX are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of TRISENOX. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g., on the long-term use of the medicine).

List of important risks and missing information	
Important identified risks	• None
Important potential risks	• Medication errors caused by confusion between the different concentrations
Missing information	• None

II.B Summary of Important Risks

Summary of Pharmacovigilance Activities and Risk Minimisation Activities by Safety Concern

Important potential risk: Medication errors caused by confusion between the different concentrations	
Evidence for linking the risk to the medicine	The product is authorised in 2 different presentations: • 10 mg/10 ml (1 mg/1 ml) of arsenic trioxide in a glass ampoule. • 12 mg/6 ml (2 mg/ ml) in a vial. There is a low theoretical potential for a medication error if a healthcare professional use the vial presentation instead of the ampoule presentation without considering the differences in concentration.
Risk factors and risk groups	Underlying systems factors have been seen to be contributors to the occurrence of medication errors. Human factors such as high perceived workload, staff health status (fatigue, stress) or interruptions/distractions during drug administration, and problems with ward-based equipment (access, functionality) have been reported as medication error general causes.
Risk minimisation measures	**Routine risk minimisation measures:** Clear quantitative composition is given in SmPC, PL, outer packaging and immediate packaging. On the outer and immediate vial packaging a red box warning highlighting the new concentration will appear for at least 6 months from launch in each European Union country. Prescription only medicine.

Important potential risk: Medication errors caused by confusion between the different concentrations	
	Additional risk minimisation measures: None.

II.C Post-Authorisation Development Plan

II.C.1 Studies Which Are Conditions of the Marketing Authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of TRISENOX.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for TRISENOX.